

ABSTRACT

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An assay method and kit is disclosed for detecting the presence of at least one  
predesignated, target antibody to a mycobacterium in a sample selected from one or more patient  
bodily fluids. The method comprises the following steps: (a) contacting the sample of one or  
5 more patient bodily fluids with at least one mycobacterium antigen on a lateral-flow assay  
membrane to bind to the target antibody in the sample; (b) previously, simultaneously or  
subsequently to step (a), binding the at least one mycobacterium antigen with a conjugated label  
producing a detectable signal; and (c) detecting the signal whereby the presence of the target  
antibody is determined in the sample by the intensity or presence of the signal. The method can  
further comprise the step of evaluating immunization status of the patient from whom the sample  
came by comparing the signal or lack thereof with immunizations previously received by the  
patient and in comparison to a known standard control. In a preferred embodiment, the  
mycobacterium antigen specifically binds to *Mycobacterium tuberculosis* specific antibodies.  
Preferably, the immunoassay of the present invention comprises a lateral-flow assay comprising  
15 a membrane, a conjugated label pad, and at least one mycobacterium antigen bound to the  
membrane. In a preferred embodiment, the at least one mycobacterium antigen is selected from  
the group consisting of 38kDa and 16kDa antigens.